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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,963	06/27/2003	Jordi Parramon	585-0031US1/05-00435-03	3067

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,963

Applicant(s)

PARRAMON ET AL.

Examiner

Deborah Malamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 August 2007.
2. Claims 1-17 are cancelled; new claims 21-35 are entered; claims 18-35 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18-21, 27, 29 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al (U.S. 6,240,316) in view of Karunasiri et al (U.S. 6,195,585). Richmond discloses (col. 3, lines 40-57) an implantable microstimulator including "(1) [a] narrow, elongated form factor suitable for implantation through the lumen of a hypodermic needle or laparoscopic instrument; (2) Electronic components encapsulated in a hermetic package made from a biocompatible material; (3) At least two electrodes on the outside of the package for the application of stimulation current to surrounding tissue; (4) An electrical coil inside the package that receives power and data by inductive coupling to a transmitting coil placed outside the body, avoiding the

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need for electrical leads to connect devices to a central implanted or external controller; and (5) Means for temporary storage of electrical power within the microstimulator.”

Richmond further discloses, (col. 7, lines 21-29) the device “includes bidirectional data telemetry plus a rechargeable battery (or other power storage component, such as an ultracapacitor) permitting autonomous function in the absence of external power transmission.” Preferably, “each BION 3 device is powered by a miniature rechargeable battery (e.g., lithium ion technology) within its hermetic package.” The examiner considers this to be a hermetically-sealed housing (1 and 2), an electronic subassembly housed within the housing (2), a first and second electrode external to the housing and electrically coupled to the electronic subassembly, an antenna coil and telemetry means (4) and a rechargeable power source means contained within the housing and connected to the electronic subassembly for providing operating power to the electronic subassembly (5).

5. Richmond discloses the claimed invention except for an electronic subassembly that measures a rectified voltage during recharging of the rechargeable power source via an external charging field, and transmits the measured voltage to one of the at least one external devices. Karunasiri however discloses (col. 6 lines 26-49) a cochlear stimulation system, including an implanted ICS and an external device, such that “the ICS processor (46) selectively monitors voltages of the electrodes and associated circuitry in the ICS processor and generates ICS status-indicating and measured signals. For example, the ICS processor monitors the voltage applied to the regulator (44), the impedance of the electrodes and other voltages within the processor to

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generate the status-indicating signals which are sent as data to the telemetry transmitter (42) for transmission to the wearable system (10). More particularly, in the cochlea stimulating system shown in FIG. 1, the signals transmitted to the ICS (12) from the wearable system include electrical power components. Such power component signals are processed (e.g., rectified) within the receiver (40) through the series regulator to generate a voltage signal which powers the ICS processor. The ICS processor selectively monitors the voltage applied to the series regulator and generates a status-indicating signal relative to such voltage which is transmitted by the telemetry transmitter and received by the telemetry receiver. As previously stated, such information is utilized in the microprocessor (30) and gate array (32) of the WP 16 to control the power level of the transmissions from the data transmitter (34) to the ICS, thereby providing a type of feedback control of the power level." Karunasiri further discloses, (Fig. 4; col. 13, lines 65-66; col. 14, lines 1-2) "The response signal that is sensed includes both the artifact associated with the stimulus and the evoked response. Monitoring of the sensed electrodes continues for about 5 ms following each stimulus." The examiner therefore notes that Karunasiri's system measure voltage both when stimulation is provided, and when stimulation is not being provided by the electronic subassembly.

6. Though Richmond discloses an implantable system for treating sleep apnea, and Karunasiri discloses a cochlear stimulation system, they both teach implantable systems for stimulating the body using an external source. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify

Richmond's rechargeable power source with Karunasiri's measured rectified voltage transmission in order to provide status feedback of the implanted device to an external device prior to stimulation of a patient.

7. Claims 22-26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al (U.S. 6,240,316) in view of Karunasiri et al (U.S. 6,195,585) and in further view of Shulman et al (U.S. 5,193,539). Regarding claims 22-23, Richmond and Karunasiri disclose the claimed invention except for a ferrite core around which the antenna coil is wrapped. Shulman however discloses, (col. 11, lines 50-52) "the coil (11) is shown wound around a ferrite core (50). Such core is cylindrical and is manufactured in two halves with a U-channel in each one." Coil 11 is a "secondary coil" within the microstimulator that "receives energy and control information from the modulated, alternating magnetic field provided by coil (1) and passes such energy and information to electronic control means which comprises power supply and data detector which, in turn, provides power to an electrode recharge current controller and stimulating electrodes (14 and 15)." Though coil 11 is not specifically named as an antenna, its purpose is identical to an antenna. Therefore, the examiner considers Schulman to teach an antenna coil wound around a ferrite core that includes a first half and a second half. See Figure 8. Shulman, Karunasiri and Richmond all teach implantable stimulators for stimulating nerves. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Richmond's antenna

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coil with Karunasiri's voltage feedback system and with Shulman's ferrite core in order to use a magnetic field to inductively charge the battery and modulate stimulation.

8. Regarding claim 24, Richmond discloses (col. 6, lines 8-11) "the microstimulator is housed within a tubular housing having a diameter no greater than about 3-4 mm, preferably only about 1.5 mm, and a length no greater than about 10-12 mm."

9. Regarding claim 25, Richmond discloses (col. 6, lines 30-39) "each implant receives the RF energy, converts it into a regulated DC supply to operate its integrated circuit chip, and stores stimulus pulse energy in a capacitor (either discrete capacitor in the hermetic package or an electrolytic capacitor formed by the stimulating electrodes themselves and the saline body fluids). When the implant receives the appropriate command data, it generates the required stimulation pulse releasing energy stored in the capacitor, and then recharging the capacitor between output pulses." The examiner considers this to be means for generating stimulation pulses that are applied through the first and second electrodes.

10. Regarding claim 26, Richmond discloses (col. 3, lines 48-50) the microstimulator includes "at least two electrodes on the outside of the package for the application of stimulation current to surrounding tissue."

11. Regarding claim 28, Richmond discloses (col. 7, lines 21-25) the device "includes bidirectional data telemetry plus a rechargeable battery (or other power storage component, such as an ultracapacitor) permitting autonomous function in the absence of external power transmission."

12. Regarding claim 30, both Richmond and Karunasiri disclose external chargers for their implantable systems.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


CARL LAYNO
PRIMARY EXAMINER


Deborah L. Malamud
Patent Examiner
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